Risk, Innovation, Diversity, Complexity

RISK, INNOVATION, DIVERSITY, COMPLEXITY: POLICY OPTIONS AND OBJECTIVES FOR STEM CELL REGULATION

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Policy Brief 5:2008

Drawing on the empirical research conducted at InnoGen and research undertaken at SCRIPT, this Policy Brief places stem cell research in the broader bioscience and health research context, highlights what have proven to be effective policy approaches in Europe, identifies some core issues in translating policy objectives into legal regulation, and offers several recommendations to facilitate the design of effective human tissue (and stem cell) regulation in Argentina.

BIOSCIENCES, HEALTH AND EXPECTATION

It is widely believed that biosciences (and resultant biotechnologies) are critical to social and economic life in the new, globalised world. Indeed, both national and supra-national governments are now seeking to use the bioscience industry as an engine for growth and competitiveness. This is especially so in the healthcare context, where sci-tech innovations are viewed as change-instigators; they are influencing our ideas of what is or might be possible from a health perspective, and they are increasingly shaping how we investigate health and how we structure healthcare delivery.

Within this healthcare context, the concept of regenerative medicine has proven very appealing and very mobilising (to industry, policy-makers and the polity more generally). Regenerative medicine is an emerging interdisciplinary field of research and clinical applications focused on the repair, replacement or regeneration of cells, tissues or organs to restore impaired function. It implicates soluble molecules, gene therapy, stem cell transplantation, tissue engineering and cell reprogramming.[1]

Regenerative medicine is an emerging concept which is proving very mobilising, not only for the economic gains to be made through the science but also the health gains to be made through the resultant treatments.

As evidenced by the above definition, a key component of regenerative medicine (and of our bioscience future more generally) is stem cell research (SCR) and innovations resulting from same. Generally, stem cells (SC) are basic cells which can give rise to specialised cells, and they are divided into adult or somatic stem cells (SSC), which are derived from particular tissue such as bone marrow or blood, and embryonic stem cells (ESC), which are derived from early stage embryos.

POLICY-MAKING PROCESSES

Stem cells are classified as adult (or somatic) and embryonic.

Modern biosciences – which incite repercussions that are potentially deep (extreme and fundamental) and long (slow-burning and long-lasting) – require

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1 H. Greenwood *et al.*, "Regenerative Medicine: New Opportunities for Developing Countries" (2006) 8 International Journal of Biotechnology 60-77.

something stronger than self-regulation,[2] and this is certainly the case in the promising but controversial field of SCR. However, the biosciences have also resulted in a general questioning of traditional top-down, hierarchical approaches to policy and regulation-making. Policy objectives are more likely to be (effectively) realised when key stakeholders (legislature, public agencies, industry, non-governmental interests, civil society more broadly) are engaged in the development of policy.

The inclusive and interactive process often called for is characterised as "governance" rather than "government"; it is a policy-making process which proceeds via multiple actors, both governmental and non-governmental, so as to facilitate the formation of productive relationships and networks, and to promote democratic processes and more nuanced policy responses.[3] The state facilitates interaction among various interests while taking steps to ensure that no single actor (eg: the church, or industry as represented by multinational corporations) dominates the process. This can be done through thoughtful framing and equitable gate-keeping of the discussion.

Biosciences like stem cell research have caused a questioning of top-down, heirarchical approaches to regulating.

In Argentina, the gate-keeping function of the governance process is appropriately managed jointly and collaboratively by the Ministries of Health and of Science & Technology, which have both identified core objectives and framing themes for the science.

TENSIONS IN THE STEM CELL ENVIRONMENT

Of course, adopting a governance approach requires the state to be prepared to deal with diversity and complexity. Some of this diversity/complexity may stem from the fragmented nature of government itself (ie: government is not a monolithic entity and therefore may have conflicting priorities for innovation promotion, on the one hand, and risk regulation on the other), but much of it will stem from the increased evidence derived from stakeholders. An example of the diversity which might be expected in the SC context is suggested by research that has already been undertaken.

Governance is a policy-making process reliant on multiple actors creating productive relationships and networks to promote democracy and responsive policy options which reflect the plurality of society.

Although debates around human ESCR are often portrayed as polarised conflict between several camps - most notably scientists, who see embryos as a cluster of cells and seek enablement, versus religiously-motivated groups, who see embryos as morally equivalent to adult humans and wish to halt research - this characterisation appears to be unfounded. Empirical research examining the positions of professionals operating in this field in the UK and Australia suggests the following: [4]

- Not all stem cell scientists are positive about the therapeutic prospects

2. A fact which Argentina has recognised as evidenced by its recent action in the sci-tech field.
3. For more on this, see C. Lyall, "Governing Genomics: New Governance Tools for New Technologies", Briefing No. 9, 2007, at http://www.genomicsnetwork.ac.uk/media/governing%20genomics.pdf
4. This empirical research, undertaken by InnoGen, comprised interviews with approximately 70 professionals (academic and industry researchers and clinicians in the UK and Australia): see A. Bruce & N. Marks, "Five Myths About Human Embryonic Stem Cell Research", Briefing No. 14, 2007, at http://www.genomicsnetwork.ac.uk/media/five%20myths%20about%20human%20embryonic%20stem%20cell%20research.pdf.

for ESCR; some see adult and ESCR as complimentary. Moreover, optimism over the therapeutic prospects of ESCR is muted in part because of the perceived gap between experimental results and clinical reality. As such, despite their excitement, many scientists wish not to raise the expectations of patients unrealistically.

Optimism over the theraputic prospects of embryonic stem cell research is muted even amoungst supporters, who anticipate that its benefits will be elsewhere

- Many stem cell scientists believe the benefits of ESCR will come not from therapies (as widely expected), but in the form of contributions to basic science, human disease modelling, bioreactor development, pharmaceutical toxicity screening, and harnessing the body's own regenerative capacities.

- Not all opponents of ESCR base their views on their religious beliefs, and not all stem cell scientists were non-religious.

- Positions on ESCR are grounded on a wider variety of issues than the moral status of the embryo. Even those who view the embryo as a ball of cells felt that it should be treated with respect, and that its destruction has to be carefully weighed against the value of potentially important health applications. Other moral issues include unnecessary hype, commercialisation of the human body, coercion and instrumentalisation of the female body, exploiting poor people, difficulty with obtaining consent, maverick scientists performing clinical trials too early, and high costs.

Positions on embryonic stem cell research are grounded on a wide variety of issues, not just the moral status of the embryo.

In short, (moral) uncertainty about hESCR does not derive solely from religious beliefs, and not all religious people are against hESCR. Moreover, there are issues other than the moral status of the embryo that will determine people's ultimate assessment of the propriety of the science. We can anticipate that this reality will be born out in Argentina.[5]

A policy-making process which captures this diversity and richness of opinion will offer a broader and more creative base from which to adapt regulation, which will concomitantly, address a wider range of concerns. It will also go some way to avoiding the unhelpful factionism identified above.

FROM POLICY TO REGULATION

A policy process which captures diversity will offer more creative and durable regulation which addresses a wider range of issues.

Through its quality, safety and effectiveness standards, and its influence on corporate strategy and sector dynamism, regulation has an important impact on the operation of (industrial) sectors and the kinds of products that are ultimately developed by that sector.[6] The regulatory system that is fashioned and how (well) it interacts with other related regimes (such as corporate

5. For example, note the contradictions apparent in the abortion setting: see L. Acero, "Gender and the New Reproductive Technologies in Latin America" (2006) 49 Development 135-140. These (cultural) contradictions are also discussed briefly in S. Harmon, "Emerging Technologies and Developing Countries: Stem Cell Research (and Cloning) Regulation and Argentina" (2008) forthcoming in Developing World Bioethics.
6. This has certainly been demonstrated in the pharmaceutical sector where the incremental accumulation of (increasingly) burdensome regulations have all but entrenched an expensive innovation model that has marginalised the role played by small and medium sized biotech entities: see J. Tait et al., "Governance, Policy and Industry Strategies: Agro-Biotechnology and Pharmaceuticals" in M. Mazzucato & G. Dosi (eds.), Knowledge Accumulation and Industry Evolution (Cambridge, CUP, 2006) 378-401, and J. Chataway et al., "The Governance of Agro- and Pharmaceutical Biotechnology Innovation: Public Policy and Industrial Strategy" (2006) 18 Technology Analysis & Strategic Management 17.

governance, intellectual property protection, etc.) will, in no small part, determine who takes the lead in conducting ESCR and developing SC products in Argentina (eg: multinationals, or smaller, more dynamic companies, or more socially-responsive public-private partnerships). If the system is too complex and therefore too onerous, many potential players will be squeezed out.

The structure and content of regulation will have an important influence on how the research sector interacts with related regimes such as corporate governance, intellectual property and health care, and will influence who takes a lead in the research industry.

As such, in formulating its regulation, Argentina must be clear about its policy goals (ie: it must imagine a good/ideal outcome for society, for public health, for sci-tech innovation, and for the industries implicated, and fashion a regulatory framework that makes it possible).[7] It must recognise that the regulation will constitute a component of a broader innovation and health delivery landscape with both formal and informal elements, and which must meet both Argentine and regional needs;[8] it must identify the links between its socio-economic, innovation, and health objectives and understand them as integrated entities.[9] In short, it must strive for a degree of "joined upness" so that actions at one healthcare innovation focal point (eg: ESCR) do not cause unanticipated problems at another (eg: human trials or commercialisation), each of which will have unique, context-dependent issues, players and risks.

Given the above, in determining its way forward in the SCR context, Argentina might consider those regulatory systems that already exist and that are relevant to this arena (eg: the human tissue and transplantation regime, the intellectual property regime, etc.), ensuring that they are complimentary and, between them, do not create unnecessary complexity. Additionally, Argentina should consider adopting regulation that *enables* changes in industry strategies, *discriminates* amongst outputs/products on socially relevant criteria so as to promote effectiveness and efficiency,[10] and, though being meticulously *risk-aware*, does not dwell overly much on risk-based constraints.[11]

Argentina must seek to achieve a degree of regulatory "joined-upness" amoungst sectors that interact at the operative level.

7. Of course, one must concede the uncertainty around trying to predict future technologies, their potential policy impacts, and their interactions with complex systems. One must also recognise that the manner of the administration of policy (and concomitant regulations) will have profound effects.
8. If Argentina wishes to maximise its benefit from its bioscience innovation (and therefore its bioscience regulation), it might also consider ways in which it might improve regional infrastructure and therefore conditions for bioscience innovation so that it retains a regional competitive advantage. For more on the regional element of innovation, see T. Papaionnou, "Regional Innovation and Pubic Policy", Briefing No. 13, 2007, at http://www.genomicsnetwork.ac.uk/media/regional%20innovation%20and%20public%20policy.pdf.
9. The benefits of early inclusion of these broader considerations is supported by empirical research conducted by InnoGen in the area of bioscience innovation: see T. Papaionnou, "Building Innovative Capabilities Through Pubic-Private Collaboration in Genomics and Biotechnology", Briefing No. 12, 2007, at http://www.genomicsnetwork.ac.uk/media/building%20innovative%20capabilities.pdf.
10. Such was recommended by J. Tait, J. Chataway & D. Wield, "Appropriate Governance of the Life Sciences – 2: The Case for Smart Regulation", InnoGen Policy Brief, 2008, who state that enabling criterion will affect the speed with which a particular regulatory policy is able to exert its influence, while the extent and appropriateness of its discrimination among outputs/products will influence its effectiveness in guiding product/process development in particular areas.
11. For a consideration of how risk was approached differently in the GM crop context as between the EU and the USA, with the consequence of dramatically different trajectories for the industry, see J. Tait, "Risk Governance of Genetically Modified Crops", Briefing No. 11, 2007, at http://www.genomicsnetwork.ac.uk/media/risk%20governance%20of%20genetically%20modified%20crops.pdf

RECOMMENDATIONS FOR ARGENTINA

Based on evidence obtained by InnoGen through a variety of projects, we can make the following recommendations:

- Policy-makers should to be prepared to deal with contradiction (ie: tensions within the opinions held by single stakeholders) and therefore complexity. As such, broad consultation combined with careful framing may help Argentina avoid the simplistic and polarising debate that has emerged in too many settings, as will the giving of space to thoughtful stakeholders to express their concerns without fear of jeopardising the SCR agenda.

Policy-makers should be prepared to deal with complexity and contradictions.

- Policy-makers should be prepared to frame the context within which the policy debates unfold (ie: write the lexicon, capture the imagination, and temper the expectation relating to the science, while engaging with concerns and desires expressed by the stakeholders and networks which choose or are invited to participate).

Policy-makers should act as issue farmers and gatekeepers.

- Policy-makers should appreciate that the primary benefits from hESCR may come in areas such as basic science, toxicity screening and drug development rather than cell therapies, and that benefits will probably be mostly medium and long term, not immediate. As such, hyperbole and (easier) short-term planning should be avoided so as to encourage more durable and flexible policy options.

Policy-makers should understand that therapies may not be the most beneficial outcome of stem cell research

- Policy-makers should make every effort to adopt a "joined up" approach; they need to be aware of the myriad ways in which SCR and its regulation interacts with other existing, emerging or planned regulatory mechanisms, and they must, of course, be careful to do so without making the endeavour too complex and burdensome.

Policy-makers should consider the place of stem cell research regulation within the constellation of relevant fields.

Regulation is not only an instrumental tool for achieving particular ends, but also a social and cultural phenomenon with its own (geographically and jurisdictionally) unique institutions, processes, concepts and ethos. As such, although not every recommendation will be exactly apposite, they are relevant not only for Argentina, but for the broader Latin American setting. Ultimately, they are founded on sound research in settings with which Argentina (and Latin America) will wish to interact and/or emulate.

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This Policy Brief forms part of the programme of work of the "Governing Emerging Technologies: Social Values and Stem Cell Regulation in Argentina" project funded by the ESRC (Award No. RES-000-22-2678) and supported by AHRC/SCRIPT and InnoGen.
For more on the GET: Social Values project, visit
http://www.law.ed.ac.uk/ahrc/esrcvaluesproject/